REMARKS

The Office Action of October 4, 2004, has been received and reviewed.

Claims 21-33, 45, and 46 are currently pending and under consideration in the above-referenced application, each standing rejected.

Reconsideration of the above-referenced application is respectfully requested.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 21-33, 45, and 46 stand rejected under the second paragraph of 35 U.S.C. § 112 for allegedly being indefinite. Specifically, it has been asserted that independent claim 21 "appears to recite that the fluorescent light is emitted as tracer molecules . . ." Office Action of October 4, 2004, page 2.

The Office's characterization of the subject matter recited in independent claim 21 is incorrect. Independent claim 21 recited that fluorescence is emitted when tracer molecules are excited. Nonetheless, to resolve the Office's confusion, independent claim 21 has been revised to replace the term "as" with "when."

It is respectfully submitted that independent claim 21 complies with the definiteness requirement of 35 U.S.C. § 112, second paragraph, and respectfully requested that the 35 U.S.C. § 112, second paragraph, rejection of independent claim 21, as well as the rejections of claims 22-33, 45, and 46 depending therefrom, be withdrawn.

The revisions to independent claim 21 do not narrow the scope thereof.

Rejections Under 35 U.S.C. § 103(a)

Claims 21-33, 45, and 46 are rejected under 35 U.S.C. § 103(a) for being drawn to subject matter which is purportedly unpatentable over the subject matter taught in U.S. Patent 4,849,340 to Oberhart (hereinafter "Oberhart"), in view of teachings from U.S. Patent 5,747,274 to Jackowski (hereinafter "Jackowski").

The standard for establishing and maintaining a rejection under 35 U.S.C. § 103(a) is set forth in M.P.E.P. § 706.02(j), which provides:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Oberhardt teaches use of fluorescent dyes with waveguides to detect the presence or absence of analytes in sample solutions. An evanescent field at an interface between the lower surface of a waveguide 10 and a reaction volume 66 contained beneath the waveguide 10 by a transparent base 30 excites the fluorescent dyes, causing them to emit fluorescent radiation. Fig. 29; col. 22, lines 14-37. That radiation is then detected by a detector 121 positioned on an opposite side of the base 30, but on the same side of the waveguide 10 as the reaction volume 66. *Id.* Thus, the fluorescent radiation that is detected does not pass through any part of the waveguide.

Oberhardt also teaches that fluorescent radiation that passes directly through a waveguide 30 may be detected by a detector 121 positioned adjacent to an opposite surface of the waveguide 30 from the surface that is exposed to a sample 66, but these teachings are limited to situations where fluorescent radiation of relatively high intensity occurs. Fig. 30; col. 22, line 56, to col. 23, line 39. The only example provided by Oberhardt is in determining hematocrit, where large quantities of the fluorescent dye are merely adsorbed to a surface of the waveguide, some of the fluorescent dye dissolves in the plasma of a blood sample, and fluorescence is measured to provide an indication of the amount of dye that remains on the surface of the waveguide 30, as well as an indication of the hematocrit (*i.e.,* percentage of red blood cells) of the blood sample. *Id.*

Jackowski teaches that fluorescently labeled antibodies, used in either competition or sandwich-type assays, may be used in optical waveguide-type assay systems. Col. 28, lines 12-21. The description of Jackowski is, however, limited to the use of such devices in a

way that fluorescent signals are "discriminated by [their] angular divergence upon exiting the waveguide." Col. 28, lines 20-21.

It is well known by those of ordinary skill in the art of optical waveguides that when fluorescent light exits a waveguide, it exits through an end or edge of the waveguide, and the angle of divergence of the exiting radiation is measured at or adjacent to that end or edge to provide some indication of the reaction that has occurred at the surface of the waveguide. This knowledge is evidence by U.S. Patent 5,166,515 to Attridge (hereinafter "Attridge"). FIG. 2(a) of Attridge and the accompanying text at col. 6, lines 13-28, indicate that fluorescent light that is emitted from fluorophores at or near a major surface of the waveguide 23 may enter the waveguide (see reference character 35) and be internally reflected within the waveguide 23. The fluorescent light 35 eventually exits the waveguide 23 through an edge 25 thereof, at which edge 25 the exit angle is determined. *See id.* Again, the measurement of the angular divergence of fluorescent light as it exits a waveguide is only the type of detection taught in Jackowski.

Independent claim 21, as amended and presented herein, is directed to an assay system for analyzing a biological liquid sample comprising, among other things, a waveguide, a light source, and a light detector. The waveguide is configured to generate an evanescent field over at least one planar surface thereof as light is directed therein. The waveguide also includes capture molecules for at least one indicator of coronary artery disease on the at least one planar surface thereof. Fluorescently labeled tracer molecules that indicate binding of the at least one indicator of coronary artery disease by a capture molecule are excited by the evanescent field. When excited, the tracer molecules emit fluorescent light. The light detector may detect the fluorescent light that passes through the major surfaces (*i.e.,* the at least one surface and an opposite surface) of the waveguide.

It is respectfully submitted that a *prima facie* case of obviousness has not been set forth against amended independent claim 21 for several reasons.

First, it is respectfully submitted that neither Oberhardt nor Jackowski teaches or suggests each and every element of amended independent claim 21. Specifically, Oberhardt and Jackowski both lack any teaching or suggestion of an assay system that includes a light detector for detecting fluorescent light, from fluorescently labeled tracer molecules, that passes through

both a planar surface and an opposite surface of a waveguide. While Oberhardt teaches that fluorescent radiation may be detected through a waveguide, those teachings are limited to instances where apparently large volumes of dye are used (*see, e.g.,* col. 23, lines 29-39), and do not include embodiments in which fluorescently labeled tracer molecules are used to indicate specific binding (*e.g.,* binding of at least one indicator of coronary artery disease with a capture molecule). The teachings of Jackowski are limited to discriminating the angular divergence of fluorescent signals as they exit the waveguide through an edge thereof. Col. 28, lines 20-21; *see also,* Attridge, FIG. 2(a); col. 6, lines 13-28. Stated another way, the fluorescent light enters the waveguide through a planar surface, but does not exit the waveguide through an opposite surface.

Second, it is respectfully submitted one of ordinary skill in the art would have no reason to expect that a combination of the teachings of Oberhardt and Jackowski, when considered in their entireties, as required by M.P.E.P. § 2143.03, would be successful. In particular, because neither reference teaches or suggests that fluorescent light emitted from a fluorescent tracer molecule that is used to indicate specific binding between an analyte and a capture molecule may be coupled back into a waveguide through a planar surface, then exit the waveguide through an opposite surface, one of ordinary skill in the art would have no reason to expect that any fluorescence emitted as a result of such a reaction would pass through both the planar surface and an opposite surface of the waveguide for detection.

Third, in view of elements of amended independent claim 21 that are neither taught nor suggested in either Oberhardt or Jackowski, as well as in the lack of a reasonable expectation that the asserted combination of teachings from Foster and Jackowski would be successful, it is respectfully submitted that one of ordinary skill in the art would not have been motivated to have combined the teachings of Oberhardt and Jackowski in the manner that has been asserted. Rather, based on the deficiencies of these references, it appears that any such motivation could only have been improperly gleaned from the disclosure of the above-referenced application.

In view of the foregoing, it is respectfully submitted that a *prima facie* case of obviousness has not been established against the subject matter recited in amended independent claim 21. Accordingly, it is respectfully submitted that, under 35 U.S.C. § 103(a), amended

independent claim 21 recites subject matter which is allowable over that taught in Foster and Jackowski.

Claims 22-33, 45, and 46 are each allowable, among other reasons, for depending either directly or indirectly from claim 21, which is allowable.

Claim 22 is additionally allowable because neither Oberhardt nor Jackowski teaches or suggests an assay system that includes a waveguide which is optically associated with a rear lens oriented for reading light passing through the waveguide to monitor coupling efficiency and beam quality. Rather than teaching an assay system that includes lenses that are oriented for "reading light," the disclosure at col. 22, lines 18-34, of Oberhardt is limited to use of a first waveguide 190 and prism 202 to introduce light into a cover (*i.e.,* waveguide) 10 and a second waveguide 191 and prism 204 to remove light from the waveguide 10.

Claim 27 depends from claim 26 and is also allowable since Oberhardt and Jackowski do not teach or suggest a controller which is configured to effect monitoring and correlating until a reliable determination is made of whether at least one indicator is coronary artery disease is present in a liquid biological sample in an amount indicative of coronary artery disease.

Claim 29 is further allowable because Oberhardt and Jackowski both lack any teaching or suggestion of a controller which is configured to effect monitoring and correlating until a reliable determination is made of whether at least one indicator is coronary artery disease is present in a liquid biological sample in an amount indicative of coronary artery disease.

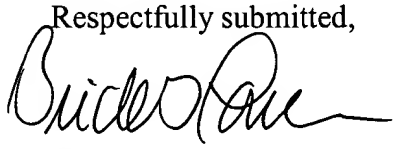
Claim 31, as amended and presented herein, is additionally allowable since neither Foster nor Jackowski teaches or suggests an assay system that includes a plurality of distinct types of fluorescently labeled tracer molecules, each corresponding to at least one indicator of coronary artery disease, and a controller that is configured to substantially simultaneously determine concentrations of a plurality of indicators of coronary artery disease.

For these reasons, withdrawal of the 35 U.S.C. § 103(a) rejections of claims 21-33, 45, and 46 is respectfully solicited.

CONCLUSION

It is respectfully submitted that each of claims 21-33, 45, and 46 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,



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